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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,530	01/14/2002	Scott P. Bruder	640100-440	5553

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,530	BRUDER ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11-20* is/are allowed.

6)☒ Claim(s) *1,2 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 6/9/05 have been entered. Currently, Claims 1, 2, 6-19 have been amended, and claim 20 is newly submitted. Claims 1, 2, and 6-20 are pending and under examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims, arguments, and terminal disclaimer will not be reiterated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 6-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25 of U.S. Patent No. 6,368,636, for reasons of record and following.

In the Remarks, Applicant argued that instant claims and the claims of the cited patent are drawn to different procedures, and thus are not obvious variation of each other.

In response, the conclusion that instant claims are obvious variations of the cited patent is drawn from the claims in light of the teaching of the specification. In the previous Office action, it is noted although the conflicting claims are not identical, they are not patentably distinct from each other because the specification of the cited patent clearly teaches administering the MSCs is the alternative for administering the supernatants of MSCs as claimed (e.g. see abstract and column 2).

For example, instant claim 1 recites "promoting hematopoietic or progenitor cell engraftment" by administering a recipient mammal in need of a therapeutically effective amount of allogenic MSCs and without a step of MHC matching. The specification of the cited '636 patent teaches, "THE INVENTORS FURTHER DISCOVERED THAT MSCS CAN SURPPRESS AN MLR BETWEEN ALLOGENEIC CELLS...THUS, MSCS DID NOT NEED TO BE MHC MATCHED TO THE TARGET CELL POPULATION IN THE MIXED LYMPHOCYTE REACTION IN ORDER TO REDUCE THE PROLIFERATIVE RESPONSE OF ALLOREACTIVE T CELLS TO MSCS" (column 5, lines 55-65), and the specification of the cited '636 patent teaches that the invention provides, "IN THE CONTEXT OF HEMATOPOIETIC STEM CELL TRANSPLANTION, FOR EXAMPLE, FROM THE MARROW AND/OR PERIPHERAL BLOOD, ATTACK OF THE HOST BY THE GRAFT CAN BE REDUCED OR ELIMINATED" (column 7, lines 32-40). Accordingly, the instantly claimed subject matter is fully disclosed in the cited patent.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,328,960, for reasons of record and following.

In the Remarks, Applicant argued that instant claims are not directed to reducing response of an effector cell against an alloantigen as recited in the claims of the cited patent, and thus are not obvious variation of each other.

In response, although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to an ordinary skilled in the art that reducing response of an effector cell against an alloantigen as recited in the claims of the cited patent would promote engraftment of hematopoietic progenitor cells bearing an alloantigen as recited in the instant claims.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-10 of U.S. Patent No. 6,797,269, for reasons of record and following.

In the Remarks, Applicant argued that instant claims are not directed to inhibiting a T cell response to an antigen as recited in the claims of the cited patent, and thus are not obvious variation of each other.

In response, although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to an ordinary skilled in the art that allogenic hematopoietic cells bearing an antigen would trigger a T cell response of the host upon transplantation, thus inhibiting a T cell response to that antigen would promote engraftment of hematopoietic progenitor cells.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claims 1, 2, and 6-10 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent Application No. 10/067,121 (US 2002/0085996), now US 6,875,430, for reasons of record and following.

In the Remarks, Applicant argued that claims of the cited patent are all drawn to reducing response of effector cells against xenoantigens, and thus are not obvious variation of each other.

In response, instant claims did not specify the origin of the hematopoietic or progenitor cell to be engrafted; thus, it encompasses xenogenic cells bearing an xenogenic antigen. Instant claims only limit the MSCs to be allogenic.

Therefore, claims of the present application and the cited patent are obvious variants, and co-extensive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

The prior rejection of claims 11-13 under 35 U.S.C. 102(e) as being anticipated by *Abatangelo et al* (US 6,482,231), is withdrawn because the cited patent does not teach transplanting allogenic MSCs without a step of MHC matching.

Claims 1, 2, and 6-10 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter, for reasons of record and following. The instant claims are obvious variants of claims of U.S. patents 6,368,636; 6,328,960; 6,797,269; and allowed U.S. patent application 10/067,121, as discussed in detail in the previous Office action and *supra*.

Applicants reiterated the arguments in the section of double patenting, which arguments have been addressed *supra*, and will not be reiterated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The prior rejection of Claim 16 under 35 U.S.C. 103(a) as being unpatentable over *Abatangelo et al* (US 6,482,231) as applied to claims 11-13 above, and further in view of *Gerson et al* (US 5,591,625), is withdrawn because the cited patents do not teach transplanting allogenic MSCs without a step of MHC matching.

Conclusion

Claims 11-20 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

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Primary Examiner
Art Unit 1633

QJL
August 11, 2005